

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
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THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

**MEMORANDUM AND PRETRIAL ORDER NO.**

Bartle, C.J.

November 13, 2007

Richard C. Gust ("Mr. Gust" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In May 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Stephen Raskin, M.D., F.A.C.C. Based on an echocardiogram dated September 9, 2002, Dr. Raskin attested in Part II of Mr. Gust's Green Form that claimant suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Dr. Raskin also attested that claimant's echocardiogram did not reveal the presence of mitral valve prolapse, which is a reduction factor that would require the payment of benefits on Matrix B-1. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b).

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2(...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

The report for claimant's echocardiogram states that the echocardiogram revealed "[m]ild mitral valve prolapse."

Mitral valve prolapse is defined as:

[A] condition where (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board - Certified Cardiologist.

Settlement Agreement § I.39. The Trust concedes that claimant is entitled to Level II Matrix Benefits. Therefore, the only issue is whether there is a reasonable medical basis for the attesting physician's finding that claimant did not have mitral valve prolapse. If paid on Matrix A-1, claimant would be entitled to benefits in the amount of \$462,103.<sup>3</sup>

In July 2005, the Trust forwarded the claim for review by Noyan Gokce, M.D., one of its auditing cardiologists. In audit, Dr. Gokce concluded that there was no reasonable medical basis for Dr. Raskin's finding that claimant did not have mitral valve prolapse concluding that:

The mitral valve appears myxomatous and there is evidence of mitral valve prolapse. The finding of mitral valve prolapse is also acknowledged in the attesting cardiologist's echo report in the medical records.

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3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b).

Based on Dr. Gokce's diagnosis of mitral valve prolapse, the Trust issued a post-audit determination that Mr. Gust was entitled only to Matrix B-1, Level II benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>4</sup> In contest, claimant argued that there was a reasonable medical basis for the attesting physician's finding that claimant did not have mitral valve prolapse as defined in the Settlement Agreement. In support, claimant submitted a Declaration from Dr. Raskin, who re-reviewed claimant's echocardiogram and opined, in relevant part, as follows:

In patients *without* mitral valve prolapse (as defined in the Green Form) mild mitral valve thickening and mild posterior systolic displacement of the mitral valve may be seen, as in Richard Gust's case. This apparent posterior displacement of the mitral valve may be normal, especially in the apical views and is a common reason for the false positive diagnosis of mitral valve prolapse. A normal mitral valve has a "saddle-shape" or "hyperbolic paraboloid" shape and failure to appreciate the "echocardiographic" appearance of the mitral valve's unique geometry is suggested by the previous echo interpretations. In addition, the degree of thickening of the mitral valve is minimal and clearly does not reach the degree required by the Freed et al., definition. Harmonic imaging is commonly used in contemporary echocardiology and some limitations imposed

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4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Gust's claim.

by the use of harmonics may result in axial blurring and apparent over-estimation of image thickness. Nevertheless, the definition used by Freed and her Framingham investigators appropriately set the degree of mitral thickening at >5mm, a degree not present in the Gust study.

Accordingly, I respectfully disagree with the Auditor's Opinion that the September 9, 2002, echocardiogram, upon which Richard Gust's Green Form is based, reveals mitral valve prolapse as defined in the Green Form. It is my opinion that there is insufficient evidence for a diagnosis of mitral valve prolapse.

Claimant argued, therefore, that he was entitled to Matrix A-1, Level II benefits.

The Trust then issued a final post-audit determination, again determining that Mr. Gust was only entitled to Matrix B-1, Level II benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Gust's claim should be paid. On January 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 6, 2006. The Show

Cause Record is now before the court for final determination.  
See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he does not have mitral valve prolapse as defined in the Settlement Agreement. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Gust argues that he has established a reasonable medical basis for the attesting physician's finding that he does not have mitral valve prolapse as defined in the Settlement Agreement. In response, the Trust argues that claimant failed to establish a reasonable medical basis for his claim because Dr. Raskin did not rebut the auditing cardiologist's finding of mitral valve prolapse or the statement on the report of claimant's echocardiogram as to mitral valve prolapse.

After reviewing the entire Show Cause Record, we find the Trust's arguments without merit. The Settlement Agreement

requires that a claim for benefits be reduced to Matrix B-1 if certain medical conditions are present. See Settlement Agreement § IV.B.2.d. In claimant's case, his mitral valve claim must be reduced to Matrix B-1 if he has mitral valve prolapse, as that condition is defined in the Settlement Agreement. See Settlement Agreement § I.39; see also id. § IV.B.2.d.(2)(c)ii)b). As noted above, mitral valve prolapse is defined as:

[A] condition where (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board - Certified Cardiologist.

Settlement Agreement § I.39.

Claimant has satisfied his burden in establishing that there was a reasonable medical basis for his attesting physician's finding that he did not have mitral valve prolapse. Unlike other reduction factors (e.g. mitral annular calcification), the Settlement Agreement sets forth a specific measurement regarding whether the presence of mitral valve prolapse requires payment of reduced benefits on Matrix B-1. In support of its position that claimant should be paid reduced Matrix Benefits, the Trust relies on its auditing cardiologist's conclusion. This conclusion, however, does not support the Trust's position because the auditing cardiologist's finding is far from conclusive because it merely states that "there is evidence of mitral valve prolapse."

Even more significantly, to reduce the payment of a mitral valve claim based on a finding of mitral valve prolapse, the Settlement Agreement explicitly requires that the parasternal long axis view show a displacement of one or both mitral leaflets greater than 2 millimeters above the atrial-ventricular border during systole, and greater than 5 millimeters leaflet thickening during diastole. See Settlement Agreement § I.39. The auditing cardiologist did not reach these two conclusions. Indeed, the auditing cardiologist merely concluded that "there is evidence of mitral valve prolapse." The auditing cardiologist did not determine separately whether claimant's level of mitral valve prolapse exceeded the required 2 millimeters in systole and 5 millimeters in diastole. See PTO No. 7327 (July 24, 2007).

In contrast, Dr. Raskin, who re-reviewed claimant's echocardiogram in light of the auditing cardiologist's findings, determined that claimant's echocardiogram did not reveal mitral valve prolapse as defined in the Settlement Agreement.<sup>5</sup> Specifically, Dr. Raskin concluded that "the definition used by Freed and her Framingham investigators appropriately set the degree of mitral thickening at >5 mm, a degree not present in the Gust study." Despite an opportunity to do so, the Trust never contested this determination of the attesting physician.

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5. As noted by claimant, the definition of mitral valve prolapse contained in the Settlement Agreement referenced the following article: Lisa A. Freed, et al., Prevalence and Clinical Outcomes of Mitral Valve Prolapse, 341 New Eng. J. Med. 1, 2 (1999). See Settlement Agreement, § I.39.



Accordingly, the Trust's determination that there is no reasonable basis for finding that claimant does not have mitral valve prolapse is erroneous.

In support of its denial, the Trust also relies on the report of claimant's September 9, 2002 echocardiogram. The echocardiogram report noted that there was "[m]ild mitral valve prolapse." The echocardiogram report, however, does not support the Trust's denial as, again, it does not reflect the necessary specific measurement of the amount of mitral valve prolapse required to reduce a claim for Matrix benefits to Matrix B-1. On this basis as well, we find that claimant has established a reasonable medical basis for his claim.

For the foregoing reasons, we conclude that claimant has met his burden in proving that there is a reasonable medical basis for finding that he does not have mitral valve prolapse as defined in the Settlement Agreement. Therefore, we will reverse the Trust's denial of Mr. Gust's claim for Matrix A-1, Level II benefits.

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CORPORATION	)	

**PRETRIAL ORDER NO.**

AND NOW, on this 13th day of November, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that the Matrix A-1, Level II claim submitted by claimant Richard C. Gust is GRANTED. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805.

BY THE COURT:

/s/ Harvey Bartle III

C.J.